IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,	)	
	)	
	)	
	)	C.A. No. 05-590-GMS
Plaintiff,	)	
	)	
v.	)	
	)	
DEXCOM, INC.,	)	
	)	
	)	
Defendant.	)	

DEXCOM, INC.'S ANSWERING BRIEF IN OPPOSITION TO ABBOTT DIABETES CARE, INC.'S MOTION FOR LIMITED JURIDICTIONAL DISCOVERY AND FOR A CORRESPONDING EXTENSION OF THE BRIEFING SCHEDULE ON DEXCOM'S MOTION TO DISMISS

ASHBY & GEDDES
Steven J. Balick (I.D. # 2114)
John G. Day (I.D. # 2403)
222 Delaware Ave., 17th Floor
P.O. Box 1150
Wilmington, DE 19899
Telephone: (302) 654-1888
Facsimile: (302) 654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com

Attorneys for Defendant
DEXCOM, INC.

Of Counsel:

David C. Doyle
M. Andrew Woodmansee
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, CA 92130-2332
(858) 720-5100

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I. INTRODUCTION

"Jurisdictional discovery" cannot change the indisputable fact that the Food and Drug Administration ("FDA") has not approved DexCom, Inc.'s ("DexCom") PMA application for its short term continuous glucose monitor ("STS"). Discovery cannot change the indisputable facts that the FDA has the authority to reject DexCom's PMA application and to request additional information—including data from *additional* clinical trials—from DexCom as a condition of approval. The jurisdictional discovery cases cited by Abbott are all off point – not a single one addresses a non-ANDA patent case in which the accused product is in the middle of the FDA review process. All material information known to DexCom concerning FDA approval of STS or related to DexCom's communications with the FDA is publicly available, as required by Federal law. Before Abbott filed suit against DexCom on August 11, 2005, it had an obligation to conduct a pre-suit investigation to determine that it in fact had a *ripe* dispute which it could bring before the Court. Abbott should not be allowed to file a complaint based on speculation and then seek discovery to support it, forcing DexCom and the Court to commence the judicial process despite the absence of an actual case or controversy.

II. ARGUMENT

A. All Material Information Concerning FDA Approval of STS Is Public Information

In determining whether a patent holder's complaint under 28 U.S.C. § 2201 satisfies the Article III case-or-controversy requirement, the Federal Circuit has held that "[t]he sole requirement for jurisdiction under the [Declaratory Judgment] Act is that the conflict be real and immediate, *i.e.,* that there be a true, actual 'controversy' required by the Act." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.,* 982 F.2d 1520, 1526 (Fed. Cir. 1992), quoting *Lang v. Pacific Marine & Supply Co., Ltd.,* 895 F.2d 761, 764 (Fed. Cir. 1990). That determination is made from the *facts* as they existed at the time Abbott filed its Complaint—August 11, 2005. *See Lang,* 895 F.2d at 764. Because DexCom does not have an FDA-approved device, there is no "accused device" to compare against

the claims of Abbott's four patents. And because it is unclear whether or when such a device will exist, Abbott's Complaint is premature. *See, e.g., Telectronics Pacing Sys.*, 982 F.2d at 1527 (dismissing declaratory judgment action as premature in light of ongoing FDA review of defendant's medical device); *NeoRX Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 214 (D. N.J. 1994) (finding that patentee failed to make a sufficient allegation of immediacy and reality because it was unclear whether FDA would grant defendant's application for license to manufacture accused product); and *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1289-90 (N.D. Cal. 1991) (dismissing declaratory judgment action as premature in light of ongoing FDA review of defendant's medical device).

Abbott characterizes the FDA approval process as a mere "theoretical" obstacle. The Court (and Abbott), of course, knows different – the Court needs no citation for the common knowledge that FDA approval of pioneering medical devices like continuous glucose monitoring systems is difficult and unpredictable.

Abbott proposes that the Court permit discovery on four irrelevant topics that relate solely to Dexcom's *internal* assessments of when and how the FDA might respond to DexCom's PMA application. *See* Motion (D.I. 9) at 4 (seeking discovery on DexCom's assessment and analysis of communications with the FDA, internal assessments of the likelihood of FDA approval, internal estimates about the projected date of product approval, and internal assessments about whether DexCom will alter its product prior to approval). As a competitor, Abbott's curiosity about what DexCom is thinking is understandable. But, what DexCom is thinking about the FDA is irrelevant. The only relevant subject is what the FDA is thinking.

As a publicly traded company, DexCom is required to disclose publicly all material information related to the FDA's investigation of its PMA application for the STS system. DexCom has regularly done so, providing disclosures to investors both in press releases and in filings with the SEC. In July of 2005, the FDA verbally notified DexCom that it would be receiving a "Major Deficiency Letter" requesting that

DexCom submit additional information to the FDA as part of the review of the PMA application for the STS system. (*See* July 25, 2005 press release, attached hereto as Ex. A). On September 12, 2005, DexCom announced publicly that it had submitted its response to the FDA's request for additional information. (*See* September 12, 2005 press release, attached hereto as Ex. B).

These are the facts. They are known to all. DexCom's internal "estimates" and "assessments" are not facts regarding FDA approval; they are a mixture of hope, concern and conjecture based on the facts known to all. DexCom internal assessments and estimates are irrelevant to whether FDA approval is actually "real and immediate." *See Lang*, 895 F.2d at 764.

B. There Is No Non-ANDA Patent Case Law That Supports Abbott's Request

Abbott cites *Canavan v. Beneficial Finance Corp.,* 553 F.2d 860, 865 (3d Cir. 1977), for the proposition that it is reversible error for a district court to grant a motion to dismiss after denying plaintiff's request for jurisdictional discovery. *Canavan* is inapposite to the facts and the law in this case. *Canavan* involved a complaint for employment discrimination under Title VII of the Civil Rights Act. In its motion to dismiss, defendant argued that it was not the plaintiff's employer, and that the court lacked jurisdiction over non-employers in Title VII cases. The district court granted defendant's motion to dismiss and denied plaintiff's request to take jurisdictional discovery. The Third Circuit reversed and ordered discovery to allow plaintiff to demonstrate that the defendant acted as an agent of plaintiff's employer and thus could be held liable under Title VII. Here, no jurisdictional discovery is necessary, as the only relevant facts—whether the FDA will approve the STS, what changes it might require to the device, and when it might approve the device—cannot be obtained from any source.

Abbott fails to cite a single case in its Motion where a court has ordered "jurisdictional discovery" in a patent case after a defendant has moved to dismiss for lack of subject matter jurisdiction because its product has not yet been approved by the

FDA. While Abbott fails to cite any such cases, numerous courts have dismissed complaints for lack of subject matter jurisdiction where defendants' device has not yet been approved by the FDA. *See, e.g., Telectronics Pacing Sys.*, 982 F.2d at 1527; *NeoRX Corp.*, 877 F. Supp. at 214; and *Intermedics, Inc.*, 775 F. Supp. at 1289-90.

Instead of addressing the on point case law, Abbott cites a series of cases, including *Glaxo, Inc. v. Novopharm, Ltd.*, and *Glaxo Group, Ltd. v. Apotex, Inc.*, that involve Abbreviated New Drug Applications ("ANDA's"). In ANDA cases, defendants have sought FDA approval for generic versions of previously approved "name brand" drugs which could be legally marketed upon expiration of plaintiffs' patents. The ANDA cases cited by Abbott are distinguishable here for at least two reasons. First, so-called generic drugs (and subjects of ANDA's in the FDA) necessarily must be *the same* as the plaintiffs' patented drugs. Second, in the cases cited by Abbott, either the defendant had announced that FDA approval was "imminent" (*Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003)), or that fact was not in dispute (*Glaxo Group, Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 (N.D. Ill. 2001)("It is indisputable, however, that defendant has submitted the ANDA, 'accompanied by data sufficient to make FDA approval imminent.'").

Unlike Abbreviated New Drug Applications, where defendant's accused product necessarily must be the same as plaintiff's patented product, it is not certain what DexCom's final STS device will look like (if one is ever approved by the FDA). Moreover, DexCom has never announced that FDA approval is imminent. In each of its public disclosures, DexCom emphasizes that the timing of FDA approval is uncertain, and that approval may not come at all. Here, given that the FDA has sent DexCom a "Major Deficiency Letter" to DexCom, approval by the FDA clearly is not imminent. *See, e.g.*, Ex. A.

C. Granting Abbott's Request Would Establish A Bad Precedent

As a plaintiff in a patent case, Abbott was required—*prior* to filing its Complaint on August 11, 2005—to conduct a reasonable inquiry (under Federal Circuit precedent

applying Rule 11 in patent cases) as to whether the accused device satisfies all claim limitations prior to asserting infringement. *See Judin v. United States*, 110 F.3d 780, 784 (Fed. Cir. 1997). In other words, Abbott was required to have (without the benefit of discovery) sufficient facts to support an actual case or controversy when it filed its complaint against DexCom. To grant Abbott's motion would be to countenance Abbott's practice of filing first and investigating later. Permitting Abbott to take discovery on the case or controversy requirement would set a bad, indeed a dangerous, precedent. That precedent would give large companies (like Abbott) a new tactic to stifle competition from new, development stage companies (like DexCom): filing a placeholder complaint during the arduous FDA approval process in the hope that "jurisdictional discovery" might provide a basis for their case, and in the certainty that the premature filing will harass the new competitor.

Abbott is using its request for "jurisdictional discovery" to gain access to highly sensitive, valuable proprietary information: DexCom's strategy for responding to FDA requests and any contingency plans DexCom may have developed to deal with delay or inability to obtain FDA approval for its STS system. That information is particularly sensitive given the fact that Abbott has been unable to secure FDA approval for its own continuous glucose monitor. TheraSense (which Abbott acquired in 2004) filed a PMA in November of 2003 for a continuous glucose monitor only to announce over a year later that additional clinical trials would be required before FDA approval. To date, Abbott has still not received FDA approval for its continuous glucose monitoring products. *See* TheraSense, Inc.'s Form 10-K Filed March 12, 2004 (attached as Ex. E to D.I. 7; DexCom's Request for Judicial Notice In Support of Motion to Dismiss) at pp. 30, 31. ("We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. Development of Navigator and other products will require additional research and development expenditures. We may not be successful in developing, marketing or

manufacturing these new products."). Abbott's FDA problems with Navigator prove that FDA approval of STS is not a "theoretical" contingency; it is real, difficult and unpredictable.

III. CONCLUSION

Because DexCom is a public company, all material information regarding the status of FDA review is already available to Abbott. No discovery is needed on this issue, and Abbott's attempt to stall this case and harass DexCom, while gaining access to DexCom's proprietary business information, should be rejected.

ASHBY & GEDDES

/s/ *John G. Day*

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
222 Delaware Ave., 17th Floor
P.O. Box 1150
Wilmington, DE 19899
Telephone: (302) 654-1888
Facsimile: (302) 654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com

Attorneys for Defendant
DEXCOM, INC.

Of Counsel:

David C. Doyle
M. Andrew Woodmansee
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San Diego, CA 92130-2332
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